Meeting held on Wednesday 2nd February

Present

Members: Dr Andrew Harris (Chair), Mrs Pauline Brown, Dr Tony Calland, Dr Mike Catchpole, Dr Patrick Coyle, Dr Tricia Cresswell, Dr Fiona Douglas, Ms Stephanie Ellis, Professor Sir Denis Pereira Gray, Mr Michael Hake, Dr Colin Harper, Professor Julia Hippisley-Cox, Professor Jane Kaye, Ms Sue Parroy, Dr Mark Taylor

In attendance: Dr Alan Doyle *(NIGB Director),* Ms Natasha Dunkley *(Approvals Manager),* Ms Claire Edgeworth *(Approvals Officer),* Ms Melanie Kingston *(Deputy Approvals Manager)*, Mr Sean Kirwan (Department of Health)

1. Welcome and apologies

Apologies were received from Professor Carol Dezateux and Mr Terence Wiseman

Ms Netta Hollings, Mr Jeremy Thorpe and Ms Clare Sanderson attended from the NHS Information Centre to provide a presentation to members entitled "Commissioning and the impact on section 251 applications" and provide background to item 4a, the Mental Health Minimum Data Set resubmission.

The Chair welcomed three new members to the Committee, Dr Colin Harper, Professor Julia Hippisley-Cox and Professor Jane Kaye, who had been appointed initially until 31st December 2011. Members were provided with a brief biography of each new member, which would be available on the NIGB website.

Conflicts of interest

Mike Catchpole declared a direct interest in item 6a, Survey of Chlamydia prevalence in England as he was employed by the Health Protection Agency and worked directly with the team involved. He therefore did not take part in any discussion on this item.

Tricia Cresswell declared an interest in item 6a, Survey of Chlamydia prevalence in England, as she was employed by the Health Protection Agency, although she was not involved with the relevant team. She did not take part in the decision taken on this item.

Jane Kaye declared an interest in item 6b, REVEAL, as she worked within the University of Oxford and had been involved in related projects. She did not take part in the decision taken regarding this item.

2. Minutes of last meeting [ECC 8-02/2010]

The minutes from the 1 December meeting were approved.

Matters arising

Update on Sexual Health Directions

Members discussed the issues arising from the sexual health directions (item 3a) at the 1 December 2010 Committee meeting. Members were informed that a meeting between Paul Jones, Chief Technology Officer, a Department of Health Legal Adviser and Professor Sir Denis Pereira Gray, Deputy Chair of ECC had been arranged on the 22nd February 2011. Members noted that they would require a written response on a legal position in order to maintain clarity on the way forward for section 251 approvals.

Action: Legal opinion to be obtained in writing following meeting.

Update on HPA annual review

The NIGB Office provided an update on the follow up meeting with the Health Protection Agency (HPA) following their annual review submission. It was agreed that further discussion would be required with the HPA and that Michael Catchpole and Tricia Cresswell should become engaged with discussions where appropriate.

Action: NIGB Office to arrange meeting with HPA representatives, Mike Catchpole, Tricia Cresswell and NIGB Office.

Review of NIGB Office processes

Members were informed that a review of the NIGB Office processes had been undertaken by Mark Reynolds, Director of Information Standards Board. Members were asked to forward any comments or suggestions to the NIGB Office.

Members noted that one of the suggestions related to increasing the amount of ECC applications to be processed via the fast track process. Members felt that caution should be taken to ensure that applications were reviewed with the required diligence.

Action: NIGB Office to circulate fast track guidance to new members.

2a. ECC Chair's Report [ECC 1-02(a)/2011]

The Chair provided a verbal update from the NIGB meeting held on the 15th December 2010. For more information on the discussions at the meeting members were advised to refer to the minutes available on the NIGB website.

2b. NIGB Office Report [ECC 1-02(b)/2011]

National Confidentiality Enquires and Mortality Audits – Data Processor change

Members were informed that the National Patient Safety Agency had recently tendered the national confidentiality enquiries and mortality audits, and that they had been renamed the Clinical Outcomes Review Programme. The National Perinatal Epidemiology Unit (NPEU) at the University of Oxford had been awarded the Maternal and Newborn Clinical Outcomes Review Programme (MN-CORP) which covered the work of the maternal mortality confidential enquiry and perinatal mortality audit which had been carried out by the Centre for Maternal and Child Health Enquiries (CMACE). It was noted that the contract would be formally taken over by the University of

Oxford/NPEU on 01 April 2011, and that this would necessarily involve a transition period. It had also been noted that the intention in future was to extend the scope of the work; however, this was not currently within the scope for the purposes of the provided section 251 support.

The University of Oxford had been asked to provide a number of documents prior to this transition taking place. Additionally, it had been highlighted that communications would need to be made to those NHS organisations submitting the relevant information as there appeared to be a possibility that data may continue to be sent to CMACE, as per pre-printed leaflets that had been sent in November 2010, although CMACE would no longer be at the premises or responsible for the management of data. Due to the sensitivity of data, it would be essential for a clear communications plan to mitigate this risk to be provided to the NIGB Office before approval could be provided.

Amendments to existing applications

ECC 4-15(c)/2009 Pilot study to compare routine assessment versus standard care in managing social difficulties in routine oncology practice

This was an extension of an existing application, Routine assessment of symptoms and functioning in cancer patients ECC 4-15(c)/2009. Researchers required access to patient identifiable data to screen for an eligible cohort, which would then be checked by the clinical care team for suitability. A member of the care team would then be introduced to the patient by a member of the clinical care team in clinic to ask whether they mind being approached by a researcher.

This study was detailed in the original application but the protocol had not yet been finalised so could not be given approval at that time. The original application was for section 251 to test one intervention and this proposed an identical method to test another as part of the same study. The same research team intended to screen the same patients' details as previously approved, so this was deemed an extension of purpose rather than additional disclosure.

This extension was approved outside of Committee.

PIAG 4-06(c)/2006 Long term sequelae of radiation exposure from computed tomography in children and adolescents

This extension request from the University of Newcastle detailed the following changes:

- The extension of the data collection period to include 1985-2010, which would result in an increase of cohort size from 250,000 to 400,000. It was noted that data collection would remain retrospective.
- The extension of the study end date to 31 September 2015 and data storage extension to 15 years from that end date.

This extension was approved via Chair's action. It was noted that data retention would continue for the stated period and that appropriate information governance techniques would be in place to separate identifiable data from clinical data as soon as possible and that analysis would take place on effectively pseudonymised data.

MR1121 Death Certificates, Cancer Registration and Hospital Episode Statistics (HES): extensions to the United Kingdom Childhood Cancer Study (UKCCS)

This extension request from the University of York was to link existing study data to HES data to permit further in-depth investigations involving mortality and cancer registration data as well as original UKCCS data. The application was for the unconsented section of the cohort only. It was

noted that the NHS Information Centre would process the data and that the applicant would receive linked files which would include only a unique study identifier rather than patient identifiable data.

Members agreed to approve this extension subject to a favourable REC opinion.

6-02 (FT1)/2010 - Sepsis - Pathophysociological & Organisational Timing: SPOT(Light)

An original condition of approval had been detailed in relation to this study:

1. Consent should be obtained where reasonably practicable if units remain in contact with patient's if/when they regain capacity.

It had been indicated that the study design had been changed to extend the cohort, and that the change was aimed at further maximizing the value of (SPOT)light in terms of determining the appropriate number of critical care beds and threshold for referral. In particular, the applicant requested waiver of this condition of approval. The justification for this was that the hospitals had indicated that seeking retrospective consent from patients (if/when they regain mental capacity either on discharge from hospital or via their GP) would not be reasonably practicable and would add an unreasonable burden preventing participation in the study. The applicant had provided details that in further discussion with scientific advisors, this issue, plus the requirement to solely seek retrospective consent from patients who regained mental capacity, had raised serious concern about the introduction of selection bias.

The email correspondence was reviewed by the Chair and he agreed that the applicant had demonstrated that it would not be reasonably practicable to obtain consent, and he had acknowledged the good supporting arguments made to justify this waiver in this specific instance.

Fast Track applications

ECC 8-02 (FT6) /2010 - Caring for seriously ill older people on acute hospital wards

This application from the University of Nottingham requested support under section 251 in order to provide a legal basis for access to medical records of 30 patients following their death on the study wards. The application presented the view that the medical records would be an important source of data about the processes of decision making and communication between professionals and relatives regarding the care of patients with and without dementia. The information extracted from the records would be anonymised at the source, and no patient identifiable details would be recorded in the data base.

In its initial consideration, Members were supportive of the application in principle, but required further clarification on a number of issues.

A letter was subsequently provided which sought to provide clarification on these issues. In considering this response, Members accepted that seeking a view from next of kin straight after a relative's death was neither feasible nor desirable and they reluctantly accepted the stated arguments around the feasibility of obtaining a view from the bereaved relatives at six weeks. However, Members were mindful that in providing approval under section 251 that its decisions could not be inconsistent with the Data Protection Act 1998. As such, Members requested that a condition of approval would be to ensure compliance with the fair processing aspect of the first principle; in other words that relatives should be informed that access had been obtained under section 251 and to provide opportunity for dissent to be registered and respected.

ECC 8-02 (FT5)/2010 - Southall And Brent REvisited. Ethnic differences in risks and outcomes of the cardiometabolic syndrome (SABRE STUDY)

This application sought an extension to application reference PIAG 2-05 (FT1)/2008 and section 251 support was required to permit access to Hospital Episode Statistics (HES) and cancer registration data in order to link to mortality data (for which section 251 support was already in place). It was noted that a substantial amendment from a research ethics committee had not yet been progressed as the outcome from the ECC assessment was to be sought in the first instance.

This had previously been considered and rejected with advice. Following a detailed resubmission, this application was approved.

Update on previous applications

ECC 2-06(a)/2009 - Small Area Health Statistics Unit (SAHSU) Health Database – extension request

Following a request from the applicant, it was agreed that the addition of MINAP to the dataset would be reviewed as an individual item, and that other clarification requests would be handled separately.

In line with the details provided in the applicant's letter, it was agreed by Chair's action that support under section 251 could be extended to include the addition of the MINAP dataset. However, this would only include postcode and date of birth (without NHS Number or address). The reason for this decision was that it was intended that the clarification over the use of addresses would be resolved separately. If successfully resolved, this decision could then be revisited to include the additional items.

ECC 7-04(a)/2010 Research Capability Programme – Health Research Support Services

This application had been provisionally approved, subject to conditions of approval around opt-out and provision of relevant patient information leaflets. The documentation was subsequently reviewed by the Chair and vice-Chair, and the documentation approved. It was acknowledged that the information provided around opt-out was not ideal, but the decision was taken that this could be refined once the activity moved past the pilot phase. However, in the documentation setting out the information governance principles, the Chair requested that the definition of clinical data be removed as it appeared to contradict the commonly held definition that clinical data had strong links to patient identifiability.

3. Presentation

3a. Commissioning and impact on section 251 applications

Mr Jeremy Thorpe, Ms Clare Sanderson and Ms Netta Hollings attended from the NHS Information Centre to give a presentation about commissioning within the NHS and the impact it would potentially have on section 251 applications. They also attended to respond to any queries around item 4a, the Mental Health Minimum Data Set application.

4. Resubmissions

4a. Mental Health Minimum Data Set [ECC 7-04(e)/2010]

This application from the NHS Information Centre required section 251 support to provide a secure legal basis for Systems and Service Delivery (SSD) to provide patient identifiable data to NHS

commissioners, and to get agreement in principle for information to be held for onward disclosure under controlled conditions. It was noted that currently pseudonymised or de-identified data was used to achieve the commissioning activities, and therefore this represented a fundamental change to current data sharing arrangements.

This application had originally been considered at the Committee meeting in December 2010, and a detailed outcome had been provided following this which set out the concerns of the Committee in seeking to recommend approval under section 251. A meeting had subsequently taken place with representatives from the NHS Information Centre, ECC Members and the NIGB Office in order to discuss further the issues involved. Members were informed that it was agreed a resubmission would be made that would address concerns of the Committee.

In reconsidering the application and further information provided, the Committee noted that pseudonymised data had previously been provided to commissioners and that the application now sought support under section 251 to permit the transfer of patient identifiable data to commissioners for payment purposes. Therefore the Committee were mindful that sufficient justification that the current system was not fit for purpose would be required.

As this was a resubmitted application the Committee reviewed the constraints set out in the initial outcome letter, and mapped the applicant's responses to these aspects.

1. Exclusion for care and treatment purposes

The Committee noted the response given for those aspects involving direct care. It was noted that some aspects would constitute primary care and the Committee were clear that any section 251 approval would not cover these purposes. However the Committee agreed they were satisfied with the applicant's responses concerning this area.

2. Public Interest

It was reiterated by the Committee that there was a public interest in ensuring that payments are made on the basis of accurate records, however, the Committee noted that this needed to be balanced against the potential for public breach of trust and reduced public engagement with NHS services if their information was used inappropriately.

The Committee considered whether this approach was the only way in which the service could be delivered, and agreed that if this was the case then this use would be in the public interest. However, the Committee could not identify evidence that other methods had been fully explored to achieve the aims. Additionally, as the use of identifiable data would involve a retrograde step in information governance terms (compared to the use of pseudonymised data), there did not appear to be a proven public interest in the retrograde step.

3. Practicable alternative

Members reviewed whether alternative approaches had been explored within the application. The discussion with attendees was useful in understanding the extent of the problem, however, the conversation indicated that a number of local data flows were taking place and the legal basis for these seemed unclear. The attendees confirmed that commissioners wished to undertake local pseudonymisation to allow the data to be linked to other datasets, although these remained unspecified. This was of particular importance to the Committee as recommendations for support under section 251 could not be used to legitimise potentially unlawful data flows; therefore it was agreed that greater clarity on this aspect would be needed. The Committee agreed that control over local activities would be required and that assurance should be provided that identifiers were only released where completely necessary.

Members also noted that in the light of the changing face of commissioning, it would be possible that certain information which a patient may not be content to share with their GP might in fact flow

to them for commissioning purposes. Given this possibility, the Committee considered that this application might set a precedent and there would be significant potential for a loss of public trust in the service if this risk were not robustly managed.

Members also queried what other UK jurisdictions were doing to manage this issue and it was confirmed that alternative processing arrangements to provide the MHMDS had not been investigated as a basis for comparison.

In line with these comments, the Committee remained unconvinced that other approaches had been sufficiently explored.

4. Compliance with the Data Protection Act 1998

Members noted there was limited information provided regarding the patient right of opt-out in line with the provisions of the Data Protection Act 1998. The Committee referred to the Research Capability Programme where this issue was seen as having the highest importance so that the activity was transparent. The Committee therefore agreed that compliance with the Data Protection Act 1998 was critical and a prerequisite for any recommendation for support under section 251. Whilst the attendees indicated that an opt-out could be provided to patients this had not been included within the application. In the absence of this information, the Committee concluded that this aspect had not been fully explored.

5. Maximum de-identification and use of minimum information

The Committee reviewed the identifiers requested and queried why NHS Number could not be used, and identifiable data items used only where there was a query. There appeared to be a lack of confidence in using the NHS Number alone, and the Committee queried whether data quality issues had arisen which then provided justification for the use of more extensive identifiers. The Committee had not been provided with any information that specified the number of instances where NHS Number would be insufficient, and therefore requested greater clarity on the extent of this problem.

In conclusion, whilst the Committee were mindful of the benefits of the activity, members noted that they were obliged to operate within the legal framework provided and agreed that the application did not provide sufficient evidence to enable them to conclude that the criteria had been met for section 251 approval. It was noted that the potential loss of trust of a particularly vulnerable group of the public in the confidentiality of their information would be very serious if section 251 were applied without clear legal justification.

It appeared to the Committee that the NHS Information Centre was making the application on behalf of another body and it was proposed that it might be helpful to arrange to talk directly with commissioners in order to establish a clear rationale for the requirements set out in the application, and members welcomed such a level of engagement.

Action: NIGB Office to notify applicant of Committee decision.

4b. National Audit of Pulmonary Hypertension [PIAG 4-05(g)/2008]

An extension request had been submitted for the above application in order to allow section 251 support to cover the release of patient identifiable data to be shared with Specialist Commissioning Groups. The request specifically detailed the inclusion of NHS number and partial post code in drug commissioning reports sent from The NHS Information Centre for health and social care (NHS IC) to the Specialised Commissioning Groups for pulmonary hypertension services. Members were informed that this had been included on the agenda as an example of an emerging

trend for the request for transfer of patient identifiable data to commissioners for payment by results purposes.

Members noted the rationale presented in the application that where there were discrepancies or deviations from recommended guidance in prescribing therapies or treatment regimens, specialist commissioners would raise these issues with the specialist centres. It was indicated that there was no mechanism to allow identification of the relevant patient and therefore no ability to deliver changes in the use of inappropriate treatments. i.e. although the commissioners could identify where inappropriate treatments were in use, the specialist centres were unable to identify the relevant patient or effect any change in treatment.

It was confirmed that sharing NHS number and the first 4 digits of the post-code would enable commissioners and clinicians to identify relevant patients where there was a deviation from national guidance in either diagnosis or treatment and ensure appropriate changes could be made. Members noted that this involved a relatively small number of cases and that patients in these circumstances may well be aware that their data would need to be shared with commissioners due to the nature of their care. It was reiterated that fair processing information would be important to ensure this was the case.

Members agreed this was an extremely reasonable purpose and therefore approved the transfer of NHS Number and first four digits of postcode to the Specialised Commissioning Groups for this purpose.

The Committee noted that as this was a previously approved application the pre-existing conditions of approval would apply.

Action: NIGB Office to notify applicant of Committee decision.

5. Annual Reviews

5a. Disclosure and use of NHS activity data in relation to commissioning and specialist mental health services; the use of data from Choose and Book and the Personal Demographic Service (Secondary Uses Service) [ECC 2-05(b)/2007]

The annual review for the above application had been initially assessed by the NIGB Office and a number of queries sent and responded to by the applicant. Due to the national importance of the Secondary Uses Service, this annual review and responses were provided to the Committee to consider at its meeting. The Committee noted that the NHS Information Centre was now the sole data controller for this application, rather than previously acting as joint data controllers.

Members assessed the documentation and also reviewed the previous conditions of approval provided by the Patient Information Advisory Group and agreed that the following clarifications were required:

1. Onward disclosure and SUS data flows

The Committee reviewed the data flow document and responses to the Office queries in relation to this aspect. Members agreed that it was essential to have clarity over all disclosures, particularly in relation to the activities covered under section 251 support. As such, Members requested that these activities be explicitly defined.

For each data flow carried out under section 251 support, members suggested that the following should be defined:

1. Each recipient organisation/classes of individuals who receive information under section 251 support

2. Where pseudonymised data would be provided to those specified in (1), specification of the provided data items
3. Where identifiable data would be made available to those specified in (1), a list of identifiers supplied
4. For each of the disclosures specified in (1) – (3), clear information on the purposes which the disclosure of data supports.

2. Previous conditions of approval

The Committee noted the previous conditions of approval provided against SUS in December 2009 and noted that they had not been reviewed in some time. Therefore it was requested that the applicant provide an update around these conditions.

The Committee agreed that support under section 251 would continue whilst responses to the following aspects were developed, with the expectation that the responses would be reviewed at the next Committee meeting.

Action: NIGB Office to notify applicant of Committee decision.

5b. Cancer Registries annual review of specific support [PIAG 03-(a)/2001]

The annual review for the cancer registries under the terms of their specific support 'Medical purposes related to the diagnosis or treatment of neoplasia was presented to the Committee for review.

The Committee agreed to recommend support for this annual review. When reviewing the report they noted that in future it would be beneficial for both the applicant and the Committee to develop a template on which to capture relevant information in order to show activities reported on met the requirements of the Health Service (Control of Patient Information) Regulations 1438/2002. Particularly Regulation 2 which indicated the categories into which the functions should fall and Regulation 7 which described the restrictions and exclusions applicable to the processing of data under the regulations. A suggested template was shared which would be discussed further with the Registries.

Action: NIGB Office to notify applicant of Committee decision

6. New applications for section 251 support

6a. Survey of Chlamydia prevalence in England [ECC 1-06(a)/2011]

Mike Catchpole declared an interest in this application and did not participate in the discussion.

This application from the Health Protection Agency (HPA) indicated a system for monitoring the prevalence of Chlamydia in England; this was required to evaluate the National Chlamydia Screening Programme.

Section 251 support was sought to permit the disclosure of contact details in relation to 17-18 year olds from Primary Care Organisation patient registers so as to facilitate the sending out of a letter with the survey and test kits. Any returns from the potential participants would be provided on a consented basis, and therefore it was noted that the consented aspect of the study would fall outside of any section 251 support.

Members noted that details of this original application had been contained within the HPA's recent annual review; however, as an ethical opinion was sought it appeared that this activity did not clearly fall under the specific Regulations and a separate application was requested. The Committee noted the speed at which an application was provided, and welcomed the applicant's engagement with this aspect.

The Committee agreed that the principle behind the activity was a worthy one and the research question had a public health benefit. In particular, Members noted that within the documentation that there was not an expectation of high returns and the extremely sensitive nature of the documentation that was to be sent out, and the Committee took this point into account when considering this application. It was also noted that PCTs would not be carrying out the work directly.

The Committee noted that strong user involvement had been carried out to support the study and commended this. However the Committee were concerned that the applicant had not fully considered the question relating to the provision of leaflets for illiterate and foreign speakers.

Members noted that the letter sent to potential participants would not be addressed from their clinical care team and that the applicant would be accessing the relevant information from potentially one of two sets of databases, one being primary care practice-derived and the other child health-derived. Particular concern was raised over accessing data from the practice derived database as opposed to the child health dataset, as a view was expressed that the cohort would have been likely to have received screening appointments from child health database, and therefore stating in the invitation letter how the information had been derived would alleviate potential concerns over potential breaches to confidentiality. A view was raised that as the letter would not be sent on local practice headed paper, there could be a perception that their doctor had breached patient confidentiality as it would be not entirely clear to participants how the contact details had been obtained. Members were concerned that this could lead to patients loosing trust in and choosing not to approach their GPs. It was understood that section 251 support was being sought to temporarily overcome this duty of confidentiality, however, the Committee balanced this with the potential perception from participants, and the impact this could have on perceived trust within the NHS against the benefits of the activity. Members also agreed that the approach would contradict the Committees principle that approaches to the patient for consent should be made by the clinical care team.

Members noted that returns were not expected to be high and queried whether the applicant would get the outcomes they required if expecting such a low response rate from the methods outlined. Members considered whether there would be any further methods of carrying out the activity not using the specified databases as section 251 support could only be provided whether there is no other practicable alternative. Members considered market research type methodology and due to the predicted lack of returns, debated whether this approach could achieve the same aims. Members requested further clarification from the applicant on whether this approach had been considered and sought information on the feasibility of pursuing this as it appeared to the Committee that this might be a reasonable approach to take.

Members felt the issue of potential loss of trust in the NHS to be a key consideration in determining whether it would be appropriate to seek to recommend support under section 251. Members consideration focused upon the potential damage that would be caused through utilising information from the databases, and whether the public interest balance was such that it would lie in favour of this access without consent. On the basis that returns were not predicted to be high, the Committee agreed that the public interest was not sufficient to warrant support when balanced against the potential detrimental loss of trust in the NHS.

As such, due to the concerns raised above, the Committee were unable to recommend support under section 251 for the activity. Whilst it was agreed that the overall purpose was reasonable, and one that would have a benefit, the balance of the public interest did not favour the arrangements set out in the application on the basis that another approach could potentially be utilised without breaching confidentiality.

Action: NIGB Office to notify applicant of Committee decision.

6b. REVEAL: Randomized Evaluation of the Effects of Anacetrapib through Lipidmodification [ECC 1-06(b)/2011]

This application from the University of Oxford required section 251 support to carry out a randomised placebo controlled trial that would compare anacetrapib 100mg once daily versus a matching placebo in approximately 30,000 patients. The study purpose was to reliably assess the safety and efficacy of this drug among people with established vascular disease.

Section 251 support was requested to enable identification of suitable participants and to facilitate a centralised invitation process. The application specified four different approaches that would be used to identify suitable participants; via hospital based records of discharge diagnoses, via access to data held at the University of Oxford on individuals who had consented to take part in the previous HPS2-THRIVE study, via consent to contact being obtained by local investigators or study nurses or by people volunteering independently to take part in the study. It was noted that section 251 was required only for the first approach, the access to hospital based records of discharge diagnoses.

It was noted that this recruitment method was very similar to previously approved applications from the CTSU – ASCEND (PIAG 4-09(h)/2003) and HPS2-THRIVE (PIAG 3-04(f)/2006) both of which had obtained section 251 support.

Members agreed this was an important clinical trial that they would wish to support, however there were some areas which the Committee agreed required additional clarification as they were not sufficiently covered within the application form.

In particular, the Committee required clarification how information about patients who had dissented in response to the initial invitation would be treated. The Committee discussed that they would ordinarily expect all information about dissenters to be destroyed on request, not just identifiable fields; therefore Members requested additional justification from the applicant for overwriting the data instead of deleting it. A view was raised that there would be the potential to carry out recruitment to the study another way and details about alternatives which may have been piloted were requested, for example the clinical care teams approaching patients at out-patient appointments

Members were uncertain what information would be received at the University of Oxford. It was noted that the application form detailed the demographic data required however it was not clear if any additional clinical information would be collected. A specific query was raised regarding whether there were any co-morbidities that would also be considered as exclusion criteria for this study and therefore which the applicant would need to know before sending out an invitation.

The Committee also requested clarification over whether the study was fully prospective or if there was a retrospective element, which would require the local investigators to review historical discharge letters.

Members noted that it was unclear from the application form how the applicant intended to comply with the Data Protection Act principles, with particular regard to the fair processing requirement. As this principle requires data subjects to be informed how their data would be used, as far as possible, Members requested details about how this could be achieved. One possibility would be to have posters readily available in waiting rooms describing the research and the right of patients or relatives to register dissent.

In conclusion Members were supportive of the application but requested the following points of clarification before approval under section 251 could be recommended:

Request for clarification

1. The applicant was asked to provide information regarding how data relating to those who had dissented would be handled, specifically for individuals that dissented after having received the initial invitation. Clarity was sought on what patients would be told about retention, and whether they would have the opportunity to have data fully deleted.
2. Clarification whether there would be any additional co-morbidities that would constitute an exclusion criteria for the study. If so, whether the applicant intended to receive any additional clinical information directly from the hospitals prior to the patient attending the screening visit.
3 Confirmation of exact data items to be disclosed from the hospital database.
4. Clarification over whether the study was a fully prospective study or whether researchers would be retrospectively looking back at hospital discharge letters in order to receive the required number of participants.
5. What information would be available to inform patients about the study.

Once satisfactory clarification over the above points had been received Members agreed to recommend approval for this application.

Action: NIGB Office to notify applicant of Committee decision

6c. National Oesophago-gastric Cancer Audit [ECC 1-06(c)/2011]

This application from the NHS Information Centre provided details of a follow-on audit of the National Oesophago-gastric (OG) cancer audit, due to commence in April 2011. The Audit would examine the quality of care received by patients with oesophago-gastric cancer in England and Wales. Linking with the first Oesophago-gastric Cancer Audit would allow results to be published on a longitudinal basis and highlight areas where care had improved and where improvement was still needed.

Section 251 support was sought to collect data on all patients aged 18 and over who had been diagnosed with oesophago-gastric cancer between 1 April 2011 and March 2014 in England and Wales. Support was also sought to permit linkage with the first National OG audit in order to carry out longitudinal analyses, and extend the cohort in April 2012 to include patients in England and Wales diagnosed with High-Grade Dysplagia. In particular, the audit requested access to NHS Number, postcode, sex, and date of birth. Linkages would be carried out with death data, HES, PEDW and the Casemix Programme within the ICNARC datasets.

The Committee agreed that this application set out a number of important purposes, and that there would be a high public interest in this activity taking place.

It was noted that the National Cancer Intelligence Network (NCIN) aimed to make available national data on radiotherapy and chemotherapy during the timeframe of the audit, and that the applicant intended to link to these datasets in future. The Committee were unclear on the implications of these specific linkages, and raised the question as to whether this would lead to re-identification of the national datasets. As the activity was not currently in place, the Committee excluded this aspect from their decision whilst further clarification was sought.

When reviewing responses around consent, members noted the statement that section 251 support would only be required in order to cover situations where the patient was too sick to ask for consent. The Committee were firmly of the view that consent did not need to be burdensome and

there appeared to be a number of opportunities within the clinical care pathway to talk to the patient. The Committee therefore welcomed that section 251 support would only be used for those patients where consent was unable to be sought. In line with this, members requested that a report be provided in the next annual review to reflect the number of patients from whom consent had been obtained in relation to the overall activity.

The Committee reviewed the responses provided by the applicant in relation to compliance with the principles of the Data Protection Act 1998. In particular, the Committee agreed that the responses did not entirely reflect the level necessary to demonstrate compliance for the specific activity. The Committee requested that this section be revised to set out how the principles would be met for the audit.

Based upon the considerations above, the Committee agreed to recommend provisional support under section 251 for those instances where it would not be possible to seek consent. This would be subject to satisfactory resolution of the requests for clarification:

Request for clarification

1. The patient information leaflet stated that NHS Number would be used as the primary linkage item, however, it was noted that the application required access to more data items. The Committee felt this to be a discrepancy in the information provided to patients and sought the applicant's comments on resolving this issue.

2. The application listed four patient identifiers, however, members noted that there was also reference to name and address. The Committee requested clarity on the identifiers that were the subject of the application. It appeared that name would used to permit linkage to death data for survival analysis, but the leaflet did not appear to cover this aspect. The Committee requested the applicant's views again on this point as the leaflet appeared to be misleading.

3. A definitive time was requested for the retention of identifiable data. The applicant was asked to confirm the retention period of identifiable data for this audit.

4. Members raised concerns that there appeared to be potential for prospective linkages to re-identify datasets, they sought the applicant's comments on the management of this risk.

Any approval would be subject to the following conditions of approval:

Conditions of approval

1. The provision of a report providing percentage details where consent was in place, this report was to be provided at the next annual review.

2. Revision of the section related to Data Protection Act 1998 compliance

3. Further linkages should be discussed with the NIGB Office, prior to the linkages taking place, to identify whether an amendment would be required.

Action: NIGB Office to notify applicant of Committee decision.

<u>Transfer of National Clinical Audit Support Programme (NCASP) cardiac audits to National Institute for Clinical Outcome Research (NICOR) at University College London (UCL)</u>

This application set out the intention of UCL to act as data processors for the cardiac audits contained within the NCASP. The current data processor for the overall NCASP audits was the

NHS Information Centre, and it was understood that the NICOR within UCL intended to carry out this role in the future in relation to the cardiac audits.

Where there is a change in data processor, the Committee agreed that the following broad aspects required assurance to be provided before any support under section 251 could be provided:

1. The acceptance of the pre-existing conditions of approval

2. Security arrangements covering the technical infrastructure and any transitional arrangements would need to be approved by Department of Health security review team.

3. Details of the governance arrangements over the handling of confidential patient information under section 251 would be required.

It was agreed that these aspects would be delegated to and managed by the NIGB Office without further recourse back to the Committee, unless a significant issue arose. Once all arrangements had been satisfactorily resolved, final approval under section 251 would be issued.

Action: NIGB Office to notify applicant of Committee decision.